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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/840,755

**Applicant(s)**

TOPOLKARAEV ET AL.

**Examiner**

PETER Y. CHOI

**Art Unit**

1794

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23 and 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23 and 29-31, claim 29 recites that the stretched precursor film comprises a blended mixture of a biodegradable polymer resin and an etched water soluble polymer resin. Applicants' specification, as originally filed, does not disclose that the stretched precursor film comprises a blend of biodegradable polymer resin and an etched water soluble polymer resin. Applicants' specification only appears to disclose that once the biodegradable polymer resin and water soluble polymer resin in the precursor film are blended, the water soluble polymer resin component may be etched (*see for example* Applicants' specification, Examples 3 and 4). Applicants' specification does not provide support for etching the water soluble polymer resin prior to blending with the biodegradable polymer resin to form the precursor film. Additionally, claims 29 and 30 recite that the stretched precursor film has a stretched length of about 100% to about 500% and about 100% to about 300% of its original

length. Applicants' specification, as originally filed, does not provide support for the claimed limitation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23 and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23 and 29-31, claims 29 and 30 recite that the stretched precursor film has a stretched length of about 100% to about 500% and about 100% to about 300% of its original length. The structure of the claimed biodegradable film is unclear. The claimed limitation appears to recite that the stretched precursor film has a stretched length. However, does that entail that the biodegradable film comprises a stretched precursor film that is necessarily about 100% to about 500% of its original length in the final product claimed, or does that entail that the biodegradable film comprises a stretched precursor film that was previously at the claimed stretched length when stretched, but that the final product does not comprise the precursor film in the stretched state? The claimed limitations are unclear.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 28-31 are rejected under 35 U.S.C. 103(a) as obvious over USPN 6,514,602 to Zhao in view of USPN 5,391,423 to Wnuk and USPN 5,800,758 to Topolkaev.

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 29-31, Zhao teaches a personal care product comprising a biodegradable film comprising a precursor film, comprising a blended mixture of a biodegradable polymer and a water soluble polymer resin (see entire document including column 2 lines 60-67, column 3 lines 20-35, column 4 line 55 to column 5 line 4, column 7 lines 35-45, column 10 line 66 to column 11 line 44). It should be noted that the biodegradable thermoplastic polymer and water-soluble thermoplastic polymer are present in the same layer so the Examiner submits that “blended mixture” is present as claimed by Applicants.

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 29-31, Zhao teaches that the water soluble polymer is a resin (Zhao, column 4 line 55 to column 5 line 4). It should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants’ specification, pages 6 and 7, Example 1). Zhao does not appear to teach that the biodegradable polymer is a resin. However, Zhao expressly incorporates by reference USPN 5,391,423 to Wnuk as teaching water soluble polymers and biodegradable polymers suitable for use in the invention of Zhao. Wnuk teaches a biodegradable, liquid impervious multilayer film for use in backsheet in disposable absorbent

products, diapers, sanitary napkins, and the like (Wnuk, Abstract, column 1 line 9 to column 5 line 7, column 5 line 40 to column 19 line 11, column 19 line 66 to column 20 line 3). Wnuk teaches that the films of Wnuk comprise two or more components selected from the group of moisture sensitive polymers, thermally sensitive polymers, and additional groups (Id., column 4 line 56 to column 5 line 7). Wnuk teaches that moisture sensitive polymers include polyvinyl alcohol resins and thermally sensitive polymers include polycaprolactone which may be used as a blend component in individual layers, or as an outer skin layer or as an inner core layer (Id., column 9 line 6 to column 10 line 18). Wnuk teaches a suitable polycaprolactone includes polycaprolactone resin (Id., column 18 line 40 to column 19 line 17). It would have been obvious to one of ordinary skill in the biodegradable article art at the time the invention was made to form the biodegradable article of the prior art, with the blended resins as taught by Wnuk, as Zhao and Wnuk are classified in the same field in the art, Zhao teaches that the polymers of Wnuk are suitable for practicing the invention of Zhao, and Zhao expressly incorporates the teachings of Wnuk by reference, and motivated by the desire of forming a conventional biodegradable article with commercially available polymer resins known in the art to be predictably suitable for forming biodegradable articles and films which are compostable and which have the properties of high strength, adequate fluid barrier, and appropriate modulus or flexibility.

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 29-31, the prior art does not appear to specifically teach that water soluble polymer resin is an etched water soluble polymer resin, and that the precursor film is a stretched precursor film having a stretched length of about 100% to about 500% and about 100% to about 300% of its original length while in contact with

an aqueous solution. However, the claimed limitations requiring the water soluble polymer resin to be etched and requiring stretching of the precursor films appear to be product by process limitations. Absent a showing to the contrary, it is Examiner's position that the article of the applied prior art (a biodegradable film comprising a biodegradable polymer resin and a water soluble polymer resin with the claimed water vapor transmission rate and thickness) is identical to or only slightly different than the claimed article. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. The burden has been shifted to Applicants to show unobvious difference between the claimed product and the prior art product. The applied prior art either anticipated or strongly suggested the claimed subject matter. It is noted that if Applicants intend to rely on Examples in the specification or in a submitted declaration to show unobviousness, Applicants should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the applied prior art.

Additionally, Topolkaraev teaches a method for making microporous films suitable for use in gowns and diapers wherein the thermoplastic films are stretched while operatively contacted with a bath of a desired surface-active liquid (Topolkaraev, column 1 line 57 to column 2 line 6, column 2 line 37 to column 3 line 47, column 14 line 13 column 13 line 45, Examples 1-12). Topolkaraev teaches that the surface-active liquid can reduce surface tension and can facilitate an improved nucleation and growth of microvoids (Id., column 14 lines 22-40).

Topolkaraev teaches that the surface-active may comprise various alcohols and organic solvents, including isopropanol with water (Id., column 14 line 62 to column 15 line 4). Topolkaraev teaches that the draw ratio is not less than 1.1 and not more than 10 (Id., column 15 lines 24-45). Topolkaraev teaches that the resulting film can exhibit various water vapor transmission rates which is in the range of about  $16,000 \text{ g/m}^2/24 \text{ hours}$  (Id., column 18 lines 8-19, Examples 1-12). It would have been obvious to one of ordinary skill in the microporous film art to form the microporous film of the prior art, wherein the micropores or microvoids are formed by the stretching technique and with the water vapor transmission rates as taught by Topolkaraev, motivated by the desire of forming a conventional microporous film with a process known in the art to form a predictably resulting microporous film which can exhibit improved wicking, can accelerate the dissolution kinetics for articles which are intended to be flushable, can help provide for improved absorbency, improved distribution of liquid, improved breathability in articles such as gowns and diapers, improved tactile and aesthetic properties, and enhanced biodegradability.

Additionally, it should be noted that etching the water soluble polymer resin and then blending the biodegradable polymer resin followed by stretching would result in a substantially similar structure and composition as the prior art since it is reasonable for one of ordinary skill in the art to expect that blending the biodegradable polymer resin and the water soluble polymer subsequent to etching would be substantially similar to a blended composition of biodegradable polymer resin and a water soluble polymer resin without etching. Additionally, Applicants' specification teaches that stretching in contact with water can accelerate dissolution and etching of the water soluble component of the film by plastically deforming the water soluble component



while it is in contact with the solvent (Applicants' specification, page 14 lines 7-25). Since the invention of the prior art is stretched while in contact with a solvent, the water soluble polymer resin of the prior art appears to be inherently etched.

Regarding claims 2, 3 and 22, the prior art teaches that the biodegradable film has a water vapor transmission rate of greater than about 2500, 3000 and 3500 g/m<sup>2</sup>/24 hours (Zhao, column 7 lines 35-45; Topolcaraev, column 18 lines 8-19, Examples 1-12). Additionally, it would have been obvious to one of ordinary skill in the biodegradable film art at the time the invention was made to optimize the water vapor transmission rate of the film since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In the present case, one of ordinary skill in the biodegradable film art would be motivated to optimize the water vapor transmission rate of the film based on the desired water vapor porosity or air permeability suitable for the desired application.

Regarding claim 4, the prior art teaches that the biodegradable polymer resin is an aliphatic polyester (Zhao, column 5 lines 40-69; Wnuk, column 5 line 40 to column 19 line 11).

Regarding claim 5, the prior art teaches that the biodegradable polymer resin is selected from the group consisting of polycaprolactone resin, polybutylene succinate resin, poly(butylene succinate-adipate) resin, polylactic acid resin, a terpolymer of terephthalic acid resin, adipic acid resin, and 1,4,-butanediol resin, and copolymers and mixtures thereof (Zhao, columns 5 and 6; Wnuk, column 5 line 40 to column 19 line 11).

Regarding claim 6, the prior art teaches that the etched water soluble polymer resin is selected from the group consisting of polyethylene oxide resin, polyethylene glycol resin, polyvinyl alcohol resin, and copolymers and mixtures thereof (Zhao, column 4 line 55 to column

5 line 4; Wnuk, column 5 line 40 to column 19 line 11). Additionally, it should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants' specification, pages 6 and 7, Example 1).

Regarding claims 8, 9 and 20, the prior art teaches that the biodegradable film has an elongation at break of greater than about 100% or greater than about 200% or greater than about 350% or greater (Zhao, column 7 lines 10-30).

Regarding claim 11, the prior art teaches that the biodegradable film includes from about 5% to about 30% water soluble polymer resin by weight of the biodegradable film (Zhao, column 2 lines 60-69).

Regarding claim 14, the prior art teaches that the biodegradable film has a thickness of from about 0.1 to 0.3 mil (Zhao, column 8 lines 1-30).

Regarding claims 17 and 18, the prior art teaches that the product is a disposable diaper, training pant, feminine pad, panty liner, incontinence product, wound dressing or delivery system (Zhao, column 3 lines 30-45; Wnuk, Abstract).

Regarding claim 23, the prior art teaches that the water-soluble polymer resin is polyethylene oxide resin, polyethylene glycol resin, or a copolymer thereof (Zhao, column 4 line 55 to column 5 line 4; Wnuk, column 5 line 40 to column 19 line 11). It should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants' specification, pages 6 and 7, Example 1).

Regarding claim 28, Zhao teaches a personal care product comprising an outer cover layer, a liquid permeable liner layer, and an absorbent body between the outer cover layer and the liner layer, wherein the liner layer is bonded to the outer cover layer and to the absorbent body, the outer cover layer comprising a blended mixture of a biodegradable polymer and a water soluble polymer, and wherein the outer cover layer comprises from about 70% to about

95% biodegradable polymer by weight of the outer cover layer (see entire document including column 2 lines 60-67, column 3 lines 20-35, column 4 line 55 to column 5 line 4, column 7 lines 35-45, column 10 line 66 to column 11 line 44). It should be noted that the biodegradable thermoplastic polymer and water-soluble thermoplastic polymer are present in the same layer so the Examiner submits that “blended mixture” is present as claimed by Applicants.

Regarding claim 28, Zhao teaches that the water soluble polymer is a resin (Zhao, column 4 line 55 to column 5 line 4). It should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants’ specification, pages 6 and 7, Example 1). Zhao does not appear to teach that the biodegradable polymer is a resin. However, Zhao expressly incorporates by reference USPN 5,391,423 to Wnuk as teaching water soluble polymers and biodegradable polymers suitable for use in the invention of Zhao. Wnuk teaches a biodegradable, liquid impervious multilayer film for use in backsheets in disposable absorbent products, diapers, sanitary napkins, and the like (Wnuk, Abstract, column 1 line 9 to column 5 line 7, column 5 line 40 to column 19 line 11, column 19 line 66 to column 20 line 3). Wnuk teaches that the films of Wnuk comprise two or more components selected from the group of moisture sensitive polymers, thermally sensitive polymers, and additional groups (Id., column 4 line 56 to column 5 line 7). Wnuk teaches that moisture sensitive polymers include polyvinyl alcohol resins and thermally sensitive polymers include polycaprolactone which may be used as a blend component in individual layers, or as an outer skin layer or as an inner core layer (Id., column 9 line 6 to column 10 line 18). Wnuk teaches a suitable polycaprolactone includes polycaprolactone resin (Id., column 18 line 40 to column 19 line 17). It would have been obvious to one of ordinary skill in the biodegradable article art at the time the invention was made to form the biodegradable article of the prior art,

with the blended resins as taught by Wnuk, as Zhao and Wnuk are classified in the same field in the art, Zhao teaches that the polymers of Wnuk are suitable for practicing the invention of Zhao, and Zhao expressly incorporates the teachings of Wnuk by reference, and motivated by the desire of forming a conventional biodegradable article with commercially available polymer resins known in the art to be predictably suitable for forming biodegradable articles and films which are compostable and which have the properties of high strength, adequate fluid barrier, and appropriate modulus or flexibility.

Regarding claim 28, the prior art does not appear to specifically teach that the outer cover layer is stretched from about 100 to about 500 percent of its original length while in contact with an aqueous solution. However, the claimed limitation requiring the outer cover layer to be stretched appears to be a product by process limitation. Absent a showing to the contrary, it is Examiner's position that the article of the applied prior art (a biodegradable film comprising a biodegradable polymer resin and a water soluble polymer resin with the claimed water vapor transmission rate and thickness) is identical to or only slightly different than the claimed article. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production.

Additionally, Topolkaraev teaches a method for making microporous films suitable for use in gowns and diapers wherein the thermoplastic films are stretched while operatively contacted with a bath of a desired surface-active liquid (Topolkaraev, column 1 line 57 to column 2 line 6, column 2 line 37 to column 3 line 47, column 14 line 13 column 13 line 45, Examples 1-12). Topolkaraev teaches that the surface-active liquid can reduce surface tension

and can facilitate an improved nucleation and growth of microvoids (Id., column 14 lines 22-40). Topolkaraev teaches that the surface-active may comprise various alcohols and organic solvents, including isopropanol with water (Id., column 14 line 62 to column 15 line 4). Topolkaraev teaches that the draw ratio is not less than 1.1 and not more than 10 (Id., column 15 lines 24-45). Topolkaraev teaches that the resulting film can exhibit various water vapor transmission rates which is in the range of about 16,000 g/m<sup>2</sup>/24 hours (Id., column 18 lines 8-19, Examples 1-12). It would have been obvious to one of ordinary skill in the microporous film art to form the microporous film of the prior art, wherein the micropores or microvoids are formed by the stretching technique and with the water vapor transmission rates as taught by Topolkaraev, motivated by the desire of forming a conventional microporous film with a process known in the art to form a predictably resulting microporous film which can exhibit improved wicking, can accelerate the dissolution kinetics for articles which are intended to be flushable, can help provide for improved absorbency, improved distribution of liquid, improved breathability in articles such as gowns and diapers, improved tactile and aesthetic properties, and enhanced biodegradability.

7. Claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 28-31 are rejected under 35 U.S.C. 103(a) as obvious over USPN 5,200,247 to Wu in view of Zhao, Wnuk, and Topolkaraev.

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 29-31, Wu teaches a personal care product comprising a biodegradable film comprising a stretched precursor film comprising a blended mixture of a biodegradable polymer and a water soluble polymer (see entire document

including column 1 line 59 to column 2 line 58, column 4 lines 3-67, column 5 and 6, Examples 1-6).

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 29-31, Wu teaches that suitable biodegradable polymers and water soluble polymers include polycaprolactone and polyvinyl alcohol. Wu does not appear to teach that the biodegradable polymer and water soluble polymers are resins. However, Zhao teaches a substantially similar biodegradable film for use in personal care products, comprising a water soluble polymer resin, such as polyvinyl alcohol or polyethylene oxide, and a biodegradable polymer (Zhao, column 2 lines 60-67, column 3 lines 20-35, column 4 line 55 to column 5 line 4, column 7 lines 35-45, column 10 line 66 to column 11 line 44). It should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants' specification, pages 6 and 7, Example 1).

Although Zhao does not appear to teach that the biodegradable polymer is a resin, Zhao expressly incorporates by reference USPN 5,391,423 to Wnuk as teaching water soluble polymers and biodegradable polymers suitable for use in the invention of Zhao. Wnuk teaches a biodegradable, liquid impervious multilayer film for use in backsheet in disposable absorbent products, diapers, sanitary napkins, and the like (Wnuk, Abstract, column 1 line 9 to column 5 line 7, column 5 line 40 to column 19 line 11, column 19 line 66 to column 20 line 3). Wnuk teaches that the films of Wnuk comprise two or more components selected from the group of moisture sensitive polymers, thermally sensitive polymers, and additional groups (Id., column 4 line 56 to column 5 line 7). Wnuk teaches that moisture sensitive polymers include polyvinyl alcohol resins and thermally sensitive polymers include polycaprolactone which may be used as a blend component in individual layers, or as an outer skin layer or as an inner core layer (Id.,

column 9 line 6 to column 10 line 18). Wnuk teaches a suitable polycaprolactone includes polycaprolactone resin (Id., column 18 line 40 to column 19 line 17). It would have been obvious to one of ordinary skill in the biodegradable article art at the time the invention was made to form the biodegradable article of the prior art, with the blended resins as taught by Zhao and Wnuk, as Wu, Zhao and Wnuk are classified in the same field in the art, Zhao teaches that the polymers of Wnuk are suitable for practicing the invention of Zhao, and Zhao expressly incorporates the teachings of Wnuk by reference, and motivated by the desire of forming a conventional biodegradable article with commercially available polymer resins known in the art to be predictably suitable and functionally equivalent for forming biodegradable articles and films which are compostable and which have the properties of high strength, adequate fluid barrier, and appropriate modulus or flexibility.

Regarding claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 29-31, the prior art does not appear to specifically teach that water soluble polymer resin is an etched water soluble polymer resin, and that the precursor film is a stretched precursor film having a stretched length of about 100% to about 500% and about 100% to about 300% of its original length while in contact with an aqueous solution. However, the claimed limitations requiring the water soluble polymer resin to be etched and requiring stretching of the precursor films appear to be product by process limitations. Absent a showing to the contrary, it is Examiner's position that the article of the applied prior art (a biodegradable film comprising a biodegradable polymer resin and a water soluble polymer resin with the claimed water vapor transmission rate and thickness) is identical to or only slightly different than the claimed article. Even though product-by-process claims are

limited by and defined by the process, determination of patentability is based on the product itself.

Additionally, Topolkaev teaches a method for making microporous films suitable for use in gowns and diapers wherein the thermoplastic films are stretched while operatively contacted with a bath of a desired surface-active liquid (Topolkaev, column 1 line 57 to column 2 line 6, column 2 line 37 to column 3 line 47, column 14 line 13 column 13 line 45, Examples 1-12). Topolkaev teaches that the surface-active liquid can reduce surface tension and can facilitate an improved nucleation and growth of microvoids (Id., column 14 lines 22-40). Topolkaev teaches that the surface-active may comprise various alcohols and organic solvents, including isopropanol with water (Id., column 14 line 62 to column 15 line 4). Topolkaev teaches that the draw ratio is not less than 1.1 and not more than 10 (Id., column 15 lines 24-45). Topolkaev teaches that the resulting film can exhibit various water vapor transmission rates which is in the range of about 16,000 g/m<sup>2</sup>/24 hours (Id., column 18 lines 8-19, Examples 1-12). It would have been obvious to one of ordinary skill in the microporous film art to form the microporous film of the prior art, wherein the micropores or microvoids are formed by the stretching technique and with the water vapor transmission rates as taught by Topolkaev, motivated by the desire of forming a conventional microporous film with a process known in the art to form a predictably resulting microporous film which can exhibit improved wicking, can accelerate the dissolution kinetics for articles which are intended to be flushable, can help provide for improved absorbency, improved distribution of liquid, improved breathability in articles such as gowns and diapers, improved tactile and aesthetic properties, and enhanced biodegradability.



Additionally, it should be noted that etching the water soluble polymer resin and then blending the biodegradable polymer resin followed by stretching would result in a substantially similar structure and composition as the prior art since it is reasonable for one of ordinary skill in the art to expect that blending the biodegradable polymer resin and the water soluble polymer subsequent to etching would be substantially similar to a blended composition of biodegradable polymer resin and a water soluble polymer resin without etching. Additionally, Applicants' specification teaches that stretching in contact with water can accelerate dissolution and etching of the water soluble component of the film by plastically deforming the water soluble component while it is in contact with the solvent (Applicants' specification, page 14 lines 7-25). Since the invention of the prior art is stretched while in contact with a solvent, the water soluble polymer resin of the prior art appears to be inherently etched.

Regarding claims 2, 3 and 22, the prior art teaches that the biodegradable film has a water vapor transmission rate of greater than about  $2500 \text{ g/m}^2/24 \text{ hours}$ , greater than about  $3000 \text{ g/m}^2/24 \text{ hours}$ , and greater than about  $3500 \text{ g/m}^2/24 \text{ hours}$  (Zhao, column 7 lines 35-45; Topolkaraev, column 18 lines 8-19, Examples 1-12). Additionally, the claimed properties are deemed to be inherent to the structure in the prior art since the prior art teaches an invention with a similar structural and chemical composition as the claimed invention (a stretched precursor film, comprising a biodegradable polymer resin and a water soluble polymer resin, wherein the biodegradable film comprises from about 70% to about 95% biodegradable polymer by weight of the biodegradable film and wherein the film is stretched from about 100 to about 500 percent of its original length).

Regarding claim 4, the prior art teaches that the biodegradable polymer resin is an aliphatic polyester (Zhao, column 5 lines 40-69; Wnuk, column 5 line 40 to column 19 line 11).

Regarding claim 5, the prior art teaches that the biodegradable polymer resin is selected from the group consisting of polycaprolactone resin, polybutylene succinate resin, poly(butylene succinate-adipate) resin, polylactic acid resin, a terpolymer of terephthalic acid resin, adipic acid resin, and 1,4-butanediol resin, and copolymers and mixtures thereof (Zhao, columns 5 and 6; Wnuk, column 5 line 40 to column 19 line 11).

Regarding claim 6, the prior art teaches that the etched water soluble polymer resin is selected from the group consisting of polyethylene oxide resin, polyethylene glycol resin, polyvinyl alcohol resin, and copolymers and mixtures thereof (Zhao, column 4 line 55 to column 5 line 4; Wnuk, column 5 line 40 to column 19 line 11). Additionally, it should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants' specification, pages 6 and 7, Example 1).

Regarding claims 8, 9 and 20, the prior art teaches that the biodegradable film has an elongation at break of greater than about 100% or greater than about 200% or greater than about 350% or greater (Wu, columns 8 and 9; Zhao, column 7 lines 10-30).

Regarding claim 11, the prior art teaches that the biodegradable film includes from about 5% to about 30% water soluble polymer resin by weight of the biodegradable film (Wu, column 4 lines 22-30, Examples 1-6; Zhao, column 2 lines 60-69).

Regarding claim 14, the prior art teaches that the biodegradable film has a thickness of from about 0.1 to 10 mil (Wu, column 7 lines 1-17, Examples 1-4, Example 6; Zhao, column 8 lines 1-30).

Regarding claims 17 and 18, the prior art teaches that the product is a disposable diaper, training pant, feminine pad, panty liner, incontinence product, wound dressing or delivery system (Wu, column 1 lines 27-40, column 2 lines 50-54; Zhao, column 3 lines 30-45; Wnuk, Abstract).

Regarding claim 23, the prior art teaches that the water-soluble polymer resin is polyethylene oxide resin, polyethylene glycol resin, or a copolymer thereof (Zhao, column 4 line 55 to column 5 line 4; Wnuk, column 5 line 40 to column 19 line 11). It should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants' specification, pages 6 and 7, Example 1).

Regarding claim 28, Wu teaches a personal care product comprising an outer cover layer, a liquid permeable liner layer, and an absorbent body between the outer cover layer and the liner layer, wherein the liner layer is bonded to the outer cover layer and to the absorbent body, the outer cover layer comprising a stretched blended mixture of a biodegradable polymer and a water soluble polymer, wherein the outer cover layer is stretched, and wherein the outer cover layer comprises from about 70% to about 95% biodegradable polymer by weight of the outer cover layer (see entire document including column 1 line 59 to column 2 line 58, column 4 lines 3-67, column 5 and 6, Examples 1-5). It should be noted that Applicants have not associated structures corresponding to the absorbent body and the liner layer. As Wu teaches that the film maybe extruded into two or three or more layers (column 4 lines 31-34), the outer extruded film is analogous to the claimed outer cover layer and the remaining layers of film are analogous to the claimed liner layer and absorbent body.

Regarding claim 28, Wu teaches that suitable biodegradable polymers and water soluble polymers include polycaprolactone and polyvinyl alcohol. Wu does not appear to teach that the biodegradable polymer and water soluble polymers are resins. However, Zhao teaches a

substantially similar biodegradable film for use in personal care products, comprising a water soluble polymer resin, such as polyvinyl alcohol or polyethylene oxide, and a biodegradable polymer (Zhao, column 2 lines 60-67, column 3 lines 20-35, column 4 line 55 to column 5 line 4, column 7 lines 35-45, column 10 line 66 to column 11 line 44). It should be noted that Polyox N-80 is a polyethylene oxide resin (Applicants' specification, pages 6 and 7, Example 1).

Although Zhao does not appear to teach that the biodegradable polymer is a resin, Zhao expressly incorporates by reference USPN 5,391,423 to Wnuk as teaching water soluble polymers and biodegradable polymers suitable for use in the invention of Zhao. Wnuk teaches a biodegradable, liquid impervious multilayer film for use in backsheets in disposable absorbent products, diapers, sanitary napkins, and the like (Wnuk, Abstract, column 1 line 9 to column 5 line 7, column 5 line 40 to column 19 line 11, column 19 line 66 to column 20 line 3). Wnuk teaches that the films of Wnuk comprise two or more components selected from the group of moisture sensitive polymers, thermally sensitive polymers, and additional groups (Id., column 4 line 56 to column 5 line 7). Wnuk teaches that moisture sensitive polymers include polyvinyl alcohol resins and thermally sensitive polymers include polycaprolactone which may be used as a blend component in individual layers, or as an outer skin layer or as an inner core layer (Id., column 9 line 6 to column 10 line 18). Wnuk teaches a suitable polycaprolactone includes polycaprolactone resin (Id., column 18 line 40 to column 19 line 17). It would have been obvious to one of ordinary skill in the biodegradable article art at the time the invention was made to form the biodegradable article of the prior art, with the blended resins as taught by Zhao and Wnuk, as Wu, Zhao and Wnuk are classified in the same field in the art, Zhao teaches that the polymers of Wnuk are suitable for practicing the invention of Zhao, and Zhao expressly

incorporates the teachings of Wnuk by reference, and motivated by the desire of forming a conventional biodegradable article with commercially available polymer resins known in the art to be predictably suitable and functionally equivalent for forming biodegradable articles and films which are compostable and which have the properties of high strength, adequate fluid barrier, and appropriate modulus or flexibility.

Regarding claim 28, the prior art does not appear to teach that the outer cover layer is stretched from about 100 to about 500 percent of its original length. However, the claimed limitations requiring the stretching of the outer cover layer appears to be a product by process limitation. Absent a showing to the contrary, it is Examiner's position that the article of the applied prior art (a biodegradable film comprising a biodegradable polymer resin and a water soluble polymer resin with the claimed water vapor transmission rate and thickness) is identical to or only slightly different than the claimed article. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.

Additionally, Topolkaraev teaches a method for making microporous films suitable for use in gowns and diapers wherein the thermoplastic films are stretched while operatively contacted with a bath of a desired surface-active liquid (Topolkaraev, column 1 line 57 to column 2 line 6, column 2 line 37 to column 3 line 47, column 14 line 13 column 13 line 45, Examples 1-12). Topolkaraev teaches that the surface-active liquid can reduce surface tension and can facilitate an improved nucleation and growth of microvoids (Id., column 14 lines 22-40). Topolkaraev teaches that the surface-active may comprise various alcohols and organic solvents, including isopropanol with water (Id., column 14 line 62 to column 15 line 4). Topolkaraev

teaches that the draw ratio is not less than 1.1 and not more than 10 (Id., column 15 lines 24-45). Topolkaev teaches that the resulting film can exhibit various water vapor transmission rates which is in the range of about 16,000 g/m<sup>2</sup>/24 hours (Id., column 18 lines 8-19, Examples 1-12). It would have been obvious to one of ordinary skill in the microporous film art to form the microporous film of the prior art, wherein the micropores or microvoids are formed by the stretching technique and with the water vapor transmission rates as taught by Topolkaev, motivated by the desire of forming a conventional microporous film with a process known in the art to form a predictably resulting microporous film which can exhibit improved wicking, can accelerate the dissolution kinetics for articles which are intended to be flushable, can help provide for improved absorbency, improved distribution of liquid, improved breathability in articles such as gowns and diapers, improved tactile and aesthetic properties, and enhanced biodegradability.

***Response to Arguments***

8. Applicants' arguments with respect to claims 2-6, 8, 9, 11, 14, 17, 18, 20, 22, 23, and 28-31 have been considered but are moot in view of the new grounds of rejection.

***Conclusion***

9. Applicants' amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PETER Y. CHOI whose telephone number is (571)272-6730. The examiner can normally be reached on Monday - Friday, 08:00 - 15:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter Y Choi /PYC/  
Examiner, Art Unit 1794

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